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INDIANAPOLIS IN 46206-6288

In re Application of	:	
MADER et al.	:	DECISION
Application No.: 10/535,002	:	
PCT No.: PCT/US2003/035041	:	
Int. Filing Date: 13 November 2003	:	
Priority Date: 22 November 2002	:	
Attorney's Docket No.: X16114	:	
For: ANTITUMOR BENZOYLSULFONAMIDES	:	

This is a decision in response to applicant's "PETITION TO THE OFFICE OF PCT LEGAL ADMINISTRATION OF THE USPTO UNDER 37 CFR 1.181 FOR REVIEW AND MODIFICATION OF THE GROUP DIRECTOR'S DECISION OF RESTRICTION REQUIREMENT UNDER UNITY OF INVENTION" filed in the United States Patent and Trademark Office (USPTO) on 16 January 2007.

**BACKGROUND**

On 13 November 2003, applicant filed international application PCT/US2003/035041, which designated the United States and claimed a priority date of 22 November 2002. A copy of the international application was communicated to the USPTO from the International Bureau on 10 June 2004. The thirty-month period for paying the basic national fee in the United States expired at midnight on 23 May 2005 (22 May 2005 being a Sunday).

On 12 May 2005, applicant filed a submission for entry into the national stage in the United States which was accompanied by, *inter alia*, the U.S. Basic National Fee and a declaration of inventors.

On 26 January 2006, the USPTO mailed a NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371 (Form PCT/DO/EO/903) according a 371(c)(1), (c)(2), and (c)(4) date of 12 May 2005.

On 16 May 2006, an Office action setting forth a lack of unity requirement between Groups I-VI was mailed.

On 16 June 2006, applicants filed a "Response to Restriction Requirement" electing

Group III with traverse. Applicants urged that the lack of unity requirement set forth in the May 16, 2006 Office action did not properly follow the PCT Markush group guidelines.

On 14 July 2006, an Office action setting forth the lack of unity requirement again and addressing applicants' traversal was mailed.

On 02 August 2006, applicants filed a "PETITION TO THE TECHNOLOGY CENTER DIRECTOR UNDER 37 CFR 1.144 FOR REVIEW AND MODIFICATION OF RESTRICTION REQUIREMENT".

On 17 October 2006, a decision was mailed indicating that the restriction requirement between Groups I-V was maintained but that Group VI (claim 4) would be rejoined with the elected compounds of Group III.

On 03 November 2006, applicants filed a "SUPPLEMENTAL PETITION TO THE TECHNOLOGY CENTER DIRECTOR UNDER 37 CFR 1.144 FOR REVIEW AND MODIFICATION OF RESTRICTION REQUIREMENT".

On 04 January 2007, a decision was mailed denying applicants' supplemental petition.

On 16 January 2007, applicants filed the instant "PETITION TO THE OFFICE OF PCT LEGAL ADMINISTRATION OF THE USPTO UNDER 37 CFR 1.181 FOR REVIEW AND MODIFICATION OF THE GROUP DIRECTOR'S DECISION OF RESTRICTION REQUIREMENT UNDER UNITY OF INVENTION".

### **DISCUSSION**

Unity of invention (not restriction) practice is applicable in national stage applications submitted under 35 U.S.C. 371. MPEP § 1893.03(d). During the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rules 13.1 and 13.2 will be followed when considering unity of invention claims. MPEP § 1850, item I.

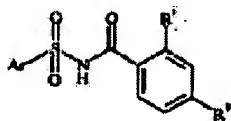
#### **PCT Rule 13.1 states**

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

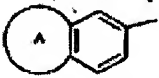
#### **PCT Rule 13.2 states**

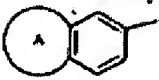
Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

As noted in the decision mailed October 17, 2006, in the Office action mailed May 16, 2006, the examiner set forth the Lack of Unity requirement as follows:



Formula 1:

Group I, claims 1-3 and 5, drawn to compounds of Formula 1 with Ar defined as , and A is phenyl, cyclopentadienyl, cyclobutyl or cyclopentyl;

Group II, claims 1-3 and 5, drawn to compounds of Formula 1 with Ar defined as , and A is benzofuryl;

Group III, claims 1-3 and 5, drawn to compounds of Formula 1 where Ar is benzothien-2-yl, benzothien-5-yl or benzothien-6-yl;

Group IV, claims 1-3 and 5, drawn to compounds of Formula 1 where Ar is thieno[3,2-b]pyridine-2-yl;

Group V, claims 1-3 and 5, drawn to compounds of Formula 1 where Ar is 1-(C<sub>1-6</sub> alkyl)indol-2-yl; and

Group VI, claim 4, drawn to a method of use of the compounds of claim 1.

The decision mailed October 17, 2006 rejoined Group VI but maintained the lack of unity requirement between Groups I-V.

Paragraph 10.17 of the PCT International Search and Preliminary Examination Guidelines discusses lack of unity under Markush practice. Paragraph 10.17(a) states,

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Paragraph 10.17(b) clarifies what is meant by "a significant structural element"

In paragraph (a)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small

portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In the instant application, all alternatives claimed are purported to have the common property or activity of being antitumor agents. Thus, item (A) is satisfied.

As to item (B), (B)(1) is applicable. The compounds share a common chemical structure, namely, benzoylsulfonamide, which occupies a large portion of their structure. I.e., benzoylsulfonamide is the common technical feature. However, that is not the end of the analysis. As noted in paragraph 10.03 of the PCT International Search and Preliminary Examination Guidelines,

In the case of independent claims to A + X and A + Y, unity of invention is present a priori as A is common to both claims. However, if it can be established that A is known, there is lack of unity a posteriori, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

Here, this common structure (or common technical feature) is well known as the basis for many sulfa drugs, as set forth in the decision mailed October 17, 2006. Additionally, as noted by the examiner in the Office action mailed May 16, 2006, the common structure is shown by Ziemer (US 6,235,680. Abstract), and in the Office Action mailed July 14, 2006, the common structure is shown by Wilson (US 5,405,727, compound F). Nor does it appear to be disputed that benzoylsulfonamide is known. Thus, there is a lack of unity because the common structure does not define a contribution over the art.

Attention is also directed to the slide presentation dated November 15, 2001, entitled "Lack of Unity in PCT Applications and 35 U.S.C. 371 Applications in Technology Center 1600" (available at <http://www.uspto.gov/web/patents/biochempharm/confnov15.htm>) reproduced in applicants' petition of November 3, 2006. The relevant slides are reproduced below.

## Markush Practice

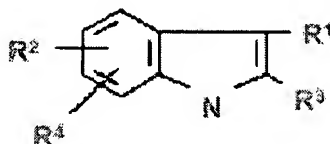
In this case the indolyl moiety is the significant structural element that is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity may be present.

But since the indolyl structure is known, it does not make a contribution over the prior art, therefore unity is lacking

## Markush Practice

Example 18 – common structure:

Claim 1: A compound of the formula:



wherein R¹ is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy and methyl; R² – R⁴ are methyl, benzyl or phenyl.

The disclosure states that the compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

The language in the second slide does not specifically state whether the "significant structural element" is "a common chemical structure which occupies a large portion of their structures" or is a case where "the compounds have in common only a small portion of their structures." Nevertheless, it seems clear that the indolyl structure occupies a large portion of the structure.

Applicants urge that the Technology Center has misinterpreted paragraph 10.17(b) of the PCT International Search and Preliminary Examination Guidelines. Specifically, it is urged that it is only in cases where the compounds have in common only a small portion of their structures that the commonly shared structure must define a contribution over the art. However, this argument is incorrect. The relevant language reads as follows

. . . or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity.

Thus, in the case where only a small portion of the structures is common to the compounds, the common portion must not only define a contribution over the art, but must also be essential to the common property or activity. As noted above in reference to paragraph 10.03 of the PCT International Search and Preliminary Examination Guidelines, the common technical feature must define a contribution over the art.

To the extent that this decision is inconsistent with any previous decisions, those portions of the previous decisions are hereby VACATED.

### **CONCLUSION**

For the reasons set forth above, applicants' petition under 37 CFR 1.181 is **DISMISSED** without prejudice.

Please direct further correspondence with respect to this matter to Mail Stop PCT, Commissioner for Patents, Office of PCT Legal Administration, P.O. Box 1450, Alexandria, Virginia 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.



Daniel Stemmer  
Legal Examiner  
PCT Legal Affairs  
Office of Patent Cooperation Treaty  
Legal Administration  
Telephone: (571) 272-3301